DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Clindamycin Capsules and Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of two supplemental abbreviated new animal drug applications (ANADAs) filed by Phoenix Scientific, Inc. One supplemental ANADA provides for an expanded dose range and revised indications wording for the oral use of clindamycin hydrochloride capsules in dogs for the treatment of certain bacterial diseases. The other supplemental ANADA provides for use of a 300-milligram capsule size.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed two supplements to ANADA 200–298 for Clindamycin Hydrochloride Capsules. One supplemental ANADA provides for an expanded dose range and revised indications wording for the oral use of clindamycin hydrochloride capsules in dogs for the treatment of certain bacterial diseases. The other supplemental ANADA provides for use of a 300-milligram capsule size. The supplemental

ANADA 200-298

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applications are approved as of April 21, 2004, and the regulations are amended in 21 CFR 520.446 to reflect their approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required for either.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.446 [Amended]

■ 2. Section 520.446 is amended by removing paragraphs (a)(2) and (b)(2); by redesignating paragraphs (a)(3) and (b)(3) as paragraphs (a)(2) and (b)(2); in paragraph (b)(1) by removing "No. 000009" and by adding in its place "Nos. 000009 and 059130"; and in newly redesignated paragraph (b)(2) by removing "(a)(3)" and by adding in its place "(a)(2)."

Dated: May 19, 2004

cv0394

May 19, 2004.

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